Essay #3:

To what extent is originality required to perform your work assignments? Describe the availability of existing practice and guidance in your area of work, and where your work has resulted in modifications to guidelines/guidance or the creation of new guidelines/guidance. GS-14 candidates should provide examples of how they used good judgement, versatility, ingenuity, and innovation to apply their expertise in situations where guidelines or methods were not clear or did not exist.

Scientific evaluation requires considerable expert judgement, in many cases extending beyond my epidemiological expertise. Each assessment has its unique set of challenges requiring versatility and good judgement to resolve. With respect to innovation, my work in systematic review was instrumental in informing and advancing methodology where guidelines were incomplete or lacking. This includes application of systematic review methods in the consideration of epidemiological evidence as well as establishing efficient workflows using specialized software applications to screen, evaluate and summarize studies. In addition, my Risk Assessment Forum (RAF) work has been a venue for using expert judgment and innovation to advance risk assessment. The following section summarizes specific examples of how I applied good judgement, ingenuity and innovation when information or guidelines were lacking.

Risk Assessment:

- Developed exposure evaluations that required expert judgements about unique exposure circumstances at a wide variety of contaminated site investigations for use by site managers and risk managers by gathering and using site-specific and activity-specific information
- Provided scientifically and statistically defensible estimates of acceptable contaminant levels where specific methodology was not available by using appropriate central tendency estimates based on the distribution of the data
- Participated in the resolution of scientific issues related to the choice of critical study, hazard identification, data modeling and uncertainty factors for at least 40 [HYPERLINK "https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments"] (PPRTVs) (see CV, Appendices) by using expertise and scientific judgement
- Displayed versatility and ingenuity by redirecting the suspended 2018 [HYPERLINK "https://www.epa.gov/iris"] (IRIS) chloroform assessment (see essay #1) to a systematic evidence map journal article in order to disseminate the assessment work done to date. As noted in the December 2019 IRIS Program Outlook,[1] the IRIS chloroform assessment was unsuspended, and the systematic evidence map is now being prepared as an IRIS assessment again. Because the work did not "stop", the timeline for producing the IRIS assessment is greatly accelerated with a draft scheduled for Agency review in 2020.

Epidemiology Support:

- Developed and tested various outcome-specific study evaluation protocols (e.g. asthma, pulmonary function, semen parameters, male reproductive hormones, diabetes, immune

[1] [HYPERLINK "https://www.epa.gov/sites/production/files/2019-12/documents/iris_program_outlook_december_2019.pdf"]

and thyroid) where guidelines for establishing such criteria did not exist. This entailed working with outside experts, application of expert judgment to develop draft criteria, and refining the criteria based on discussions with peers. Once developed and used in assessment products these protocols then become available to the public.

- Used expert judgement, flexibility and innovation in applying epidemiology expertise to support a quick turnaround for Office of Pollution Prevention and Toxics (OPPT) regulatory requirements by suggesting changes to criteria and to data extraction forms used in evaluation of epidemiology studies (award received)

Systematic Review:

- Enhanced systematic review standard operating procedures (SOPs) for use by IRIS, OPPT, states and the Center for Public Health and Environmental Assessment (CPHEA) by modifying critical elements for testing Populations, Exposures, Comparisons, and Outcomes (PECOs), screening strategies, literature inventories and study evaluations through written instructions, presentations and workflows. Having consistent SOPs developed through collaboration has had significant impact on fostering consistency in the application of systematic review across different assessment programs. In addition, many of these SOPs utilize specialized software that reduces the time and cost of conducting the assessment.
- Applied systematic review methods to the IRIS chloroform assessment, suspended assessments of ammonia (oral) and uranium, and systematic evidence maps for phthalates, acrolein, and naphthalene by tailoring an innovative approach (evidence mapping) for rapid systematic review of assessments
- Developed and improved the practical application of the systematic review process by identifying critical flaws in systematic review components and modifying them
- Assisted in developing and applying iterative detailed strategies for study evaluation and data extraction which resulted in improved evaluations
- Organized pilots for testing PECOs, screening strategies, literature inventories and study evaluations and modified elements as needed for better efficiency
- Provided systematic review support for OPPT to help them meet regulatory requirements associated with OPPT chemical risk evaluation, a high priority for the Agency requiring a rapid turnaround by using creativity and innovation to meet tight deadlines (award received)

Risk Assessment Forum (RAF):

- As a member of the RAF Cumulative Risk Assessment (CRA) Technical Panel I chaired the Subcommittee on Research Planning for CRA from 2004 - 2009 and was responsible for identifying needs, issues and priorities of the Regions and Program offices as they relate to CRA and for providing direction, priorities and perspective to CRA Research Planning where none existed before.
- As a member of the RAF CRA Writing Team, I assisted in the development of the current draft CRA Guidance titled '*Guidance for Cumulative Risk Assessment; Planning and Problem Formulation, (revised Risk Assessment Forum Review Draft, 2019)*'. This describes steps for the planning and problem formulation of CRAs and offers guidance for when such assessments might be appropriate. It updates and supersedes the *1997* [HYPERLINK "http://www.epa.gov/sites/production/files/2015-01/documents/cumrisk2_0.pdf"

\h]. This guidance places emphasis on providing a uniform yet flexible CRA planning and problem formulation methodology to be used as a decision support tool for risk management at the Agency, thus advancing risk assessment.

- As a member of the Probabilistic Risk Analysis (PRA) Technical Panel I advanced the field of risk assessment and helped to inform decision making at the Agency, by contributing to innovative efforts put forth in two white papers on guidance for PRA [2,3] (see file:_____).
- Authored, with other Agency scientists, the *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Inter-Species and Intra-Species Extrapolation*[4] where none existed (see file:_____). This guidance describes an innovative approach for identifying and using pertinent information for developing data-derived extrapolation factors (DDEFs) for the purposes of developing Reference Doses (RfDs), Reference Concentrations (RfCs), or related metrics (such as hazard index, margin of exposure) in lieu of using default values and processes thereby reducing uncertainty in RfD and RfC values, thus advancing risk assessment.

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[2] U.S. EPA, Office of the Science Advisor, Risk Assessment Forum. White Paper: Probabilistic Risk Assessment to Inform Decision Making: Frequently Asked Questions. (2014). EPA/100/R-09/001B. Washington, D.C.: Risk Assessment Forum, Office of the Science Advisor, USEPA.
[HYPERLINK "http://epa.gov/raf/prawhitepaper/index.htm"]

[3] U.S. EPA, Office of the Science Advisor, Risk Assessment Forum. White Paper: Probabilistic Risk Assessment Methods and Case Studies. (2014). EPA/100/R-14/004 [HYPERLINK "https://www.epa.gov/sites/production/files/2014-12/documents/raf-pra-white-paper-final.pdf"]

[4] [HYPERLINK "https://www.epa.gov/sites/production/files/2015-01/documents/ddef-final.pdf"]